Public Health Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES

M2229A

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-16

December 1, 1998

Stanley J. Wellington, President
W&W International Medical Research Group
301 Magnolia Avenue
Merritt Island, Florida 32952

Dear Dr. Wellington:

We are writing to you because on September 21, 1998, FDA Investigator Ronnie E. Jackson collected information that revealed serious regulatory problems involving your promotion and distribution of the product, Cantron, as well as the Zapper-Plus (W&W 200), the ElectroMagic Model-D Rife Instrument, aka, "Astropulse Model D" (W&W 300), and the Envira EMR Protection Plus (W&W 400) devices.

The promotional material for "Cantron" and the promotional literature titled "AIDS Answer and More" claims "Cancell" (now re-named Cantron)... user proven to be 99% effective on removing HIV and AIDS virus from the blood with 28 days. Just as effective on cancer, lupus, tumors, heart disorders, clogged arteries, Parkinsons..." as well as numerous "testimonials" claiming that Cancell/Cantron cured cases of lung cancer, ovarian cancer, globlastoma, colon cancer, prostate cancer, lymphoma, leukemia, cervical cancer, multiple sclerosis, arthritis, and so forth.

Based on the above claims, this product is a drug within the meaning of section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act) and, a "new drug" within the meaning of section 201(p). Therefore, it may not be marketed in the United States without an approved New Drug Application (NDA) pursuant to section 505(a) of the Act.

This drug is also misbranded within the meaning of section **502(f)(1)** of the Act in that the labeling fails to bear adequate directions for use. The labeling is false and misleading as it suggests the product is safe and effective for its intended uses when, in fact, this has not been established section 502(a) of the Act.

Under the Act, the devices identified as W&W 200, W&W 300 and W&W 400 are considered to be medical devices that are used to diagnose or treat a medical condition or to affect the structure or function of the body.

The inspection revealed that your devices are adulterated within the meaning of section **501(f)(1)(B)** in that the devices are classified under section 513(f) into class III, which under section 515(a) are required to have in effect an approved application for premarket approval, and which are not exempt from section 515 under section 520(g).

The devices, Zapper-Plus (W&W 200), Electromagic Model-D Rife Instrument (W&W 300), and Envira EMR Protection Plus (W&W 400), are misbranded within the meaning of section **502(o)**in that a notice or other information respecting the devices was not provided to the FDA as required by Section 510(k).

This letter is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the awards of contracts. Additionally, no premarket submissions for drugs or devices will be cleared until the violations have been corrected. Also, no requests for Certificates of Products For Export will be approved until the violations related to the subject drugs or devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administratrion without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the timeframes within which the corrections will be completed, (2) any documentation indicating the correction has been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to Martin E. Katz, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4729.

Sincerely,

Edward R. Petties for

Douglas D. Tolen
Director, Florida District